



May 29, 2002

BY FACSIMILE

Dr. Evangeline Tsibris Cummings
Office of Environmental Information
U.S. Environmental Protection Agency
1200 Pennsylvania Avenue, SW
MC2842T
Washington, DC 20460

Re: Draft Guidelines for Ensuring and Maximizing the Quality,
Objectivity, Utility, and Integrity of Information Disseminated by
the Environmental Protection Agency

Dear Dr. Cummings:

I write on behalf of the Battery Council International ("BCI")¹ to express our views on the Draft Guidelines for Ensuring and Maximizing the Quality, Objectivity, Utility, and Integrity of Information Disseminated by the Environmental Protection Agency (hereinafter "Data Quality Guidelines"). <http://www.epa.gov/oei/qualityguidelines/> (visited May 10, 2002).

BCI believes that the implementation of the Office of Management and Budget Guidelines for Ensuring and Maximizing the Quality, Objectivity, Utility, and Integrity of Information Disseminated by Federal Agencies ("OMB guidelines") provides the Environmental Protection Agency ("EPA") with an important and unique opportunity to ensure that the scientific information it disseminates and bases its regulatory decisions upon is of the highest quality and caliber. Unfortunately, EPA has been less than diligent in ensuring that its Data Quality Guidelines are consistent with the OMB guidelines. As a result, EPA's Data Quality Guidelines, in their current form, are unlikely to achieve the key intent of the OMB guidelines of ensuring the "quality" of the data used by the Agency in its regulatory decisions. <http://www.whitehouse.gov/omb/fedreg/reproducible.html>, page 3 of 19 (visited April 14, 2002). This suggests that EPA may not be as serious about implementing the OMB guidelines as it should be. BCI hopes this is not the case, and suggests changes (below) to the Data Quality

¹ BCI is a not-for-profit trade association representing commercial entities involved in the manufacture, distribution, sale and recycling of lead-acid batteries. BCI's members include manufacturers and distributors of lead-acid batteries and the secondary smelters that reclaim or recycle lead batteries once they are spent. BCI's membership represents more than 99 percent of the nation's domestic lead battery manufacturing capacity and more than 90 percent of the nation's recycling or secondary smelting capacity.

Guidelines that will make them more consistent with the OMB guidelines and ensure that the Agency's scientific information is of the highest quality.

COMMENTS

1. Basic Standard of Quality

As a general rule, BCI believes that there is not a single, basic standard of quality that can be meaningfully articulated to cover all conceivable forms of information disseminated by the Environmental Protection Agency ("EPA"). We do, however, agree with OMB that "[t]he more important the information, the higher the quality standards to which it should be held. . . ." 67 Fed. Reg. 8452.

As a practical matter, most of the information EPA disseminates constitutes "information risks to human health, safety and the environment." For such information, the OMB guidelines require EPA to adopt (or adapt) two Safe Drinking Water standards. First, the information must be based upon:

(i) the best available, peer-reviewed science and supporting studies conducted in accordance with sound and objective scientific practices; and (ii) data collected by accepted methods or best available methods (if the reliability of the method and the nature of the decision justifies use of the data).² 42 U.S.C. §300g-1(b)(3)(A).

Second, the Agency must "ensure that the presentation of information [risk] effects is comprehensive, informative and understandable" by specifying in a document made available to the public and in support of a regulation:

(i) each population addressed by any estimate of public health effects;

(ii) the expected risk or central estimate of risk for the specific populations;

(iii) each appropriate upper-bound or lower-bound estimate of risk;

² "Best available" refers to at the time the regulatory decision is made. See .S. Rep. No. 104-169 at 28-29 (1995) ("the Administrator has a duty to seek and rely upon the best available science and information to support these decisions. . . . If an accepted method is not available for a particular task, the Administrator may rely on the best available method, provided that the *reliability of that method is appropriate to the decision that is to be informed or supported by the data.*") emphasis added.

(iv) each significant uncertainty identified in the process of the assessment of public health effects and studies that would assist in resolving the uncertainty; and

(v) peer-reviewed studies known to the Administrator that support, are directly relevant to, or fail to support any estimate of public health effects and the methodology used to reconcile inconsistencies in the scientific data. 42 U.S.C. §300g-1(b)(3)(B).

BCI was shocked to learn that EPA's Data Quality Guidelines attempt to limit the reach of these standards to assessments involving only human health. While the OMB guidelines provide the Agency with flexibility to adopt or adapt the Safe Drinking Water Act principles to risk assessments performed by the agencies, they are intended to be applicable "to analysis of risks to human health, safety and the environment maintained or disseminated by the agencies" without limitation. <http://www.whitehouse.gov/omb/fedreg/reproducible.html>, page 12 of 19. Nowhere, do the OMB guidelines allow EPA to limit the reach of these standards to only human health risk assessments.

Indeed, BCI believes it is vitally important for EPA to adopt these standards completely as they go to the heart of what EPA does: the scientific and technical data that underlie its decision making. For example, when the Agency develops regulations based on risk (*e.g.*, residual risk standards under Clean Air Act § 112(f)(2)) these standards are likely to be relevant and should be addressed. Likewise, when the Agency develops health effects benchmarks for particular chemicals or substances (*e.g.*, RfCs, RfDs and CSFs), it should address each element of the above standards and apply a vigorous weight of the evidence methodology to reconcile inconsistencies in the literature. In practice, EPA has provided this information to varying degrees, but there is no inherent reason why it could not or should not do so consistently now. The important exercise of doing so now will ensure use of the "best available peer-reviewed science."

2. What Constitutes Influential Information

OMB's guidelines apply a higher standard for "influential scientific, financial, or statistical information." OMB defines information as influential if "the agency can reasonably determine that dissemination of the information will have or does have a clear and substantial impact on important public policies or important private sector decisions." Paragraph V. 9. found at <http://www.whitehouse.gov/omb/fedreg/reproducible.html>, page 18 of 19.

EPA's Data Quality Guidelines define "influential" as: top Agency actions (*i.e.*, rules, substantive notices, policy documents, studies guidance) that demand ongoing involvement of the Administrator's office and extensive cross-Agency involvement; information disseminated in support of OMB "Economically Significant" actions (*i.e.*, agency actions likely to have an annual

effect on the economy of \$100 million or more or adversely affect in a material way the economy, a sector of the economy, productivity, competition, jobs, the environment, public health, safety, or State, local, or tribal governments or communities); and work products under peer-review as called for under the Agency's Peer Review Policy, which is intended to include major scientific and technical work products and economic analysis used in decision making. <http://www.epa.gov/oei/qualityguidelines/>, at 18.

BCI believes EPA's definition of "influential" is far too narrow. We recommend that, in addition to the categories above, the Agency define the following categories of information as influential:

- Chemical information contained in the Integrated Risk Information System (IRIS). Information in IRIS is used across EPA program offices and by state governments for regulatory standard setting.
- Chemical and substance (*e.g.*, metals) classifications (*e.g.*, EPA's list of chemicals and substances that are persistent, toxic, and bioaccumulative; EPA's classification of chemicals and substances as actual or suspected carcinogens; any characterization of chemicals as actual or suspected endocrine disrupters). In some cases such classifications are part of IRIS. In other cases, such classifications are part of assessments that are not part of IRIS and they may have significant impact on regulations or product use.
- Risk assessments likely to have a clear and substantial impact on particular chemicals or substances, products or processes (*e.g.*, assessments of whether dioxin or lead cause cancer, registration of pesticides, etc.).
- Models and similar "information products" designed to characterize the risk posed by chemicals or substances, facilities, products, or by ambient conditions at a particular location or a defined category of locations (*e.g.*, municipal solid waste landfills) and the results of these tools.
- Tools that rank facilities, organizations or localities by environmental performance or quality factors.
- Site specific risk assessments conducted under the Resource Conservation and Recovery Act or the Comprehensive Environmental Response, Compensation and Liability Act entailing total cleanup costs in excess of \$5 million.
- Data developed by external sources (*e.g.*, states, localities, etc.) that would fall within any one of the above categories if it is used or adopted by EPA for a specific purpose.

We recognize that it would be impractical for the Agency to make a comprehensive determination about “influential” information for all of the scientific, financial and statistical information it disseminates. Therefore, BCI recommends that EPA define some information as categorically influential (as described above), and use its discretionary authority to classify other information as influential where that information is likely to have a substantial impact upon the regulated community.

3. Mechanisms for Timely Correction

a. Appropriate Time Periods for Agency Decisions

EPA’s Draft Data Quality Guidelines contain no time periods for when decisions will be made by the Agency on complaints. This is inconsistent with the OMB guidelines. Those guidelines require agencies to “specify appropriate time periods for agency decisions on whether and how to correct the information.” Paragraph III.3.i found at <http://www.whitehouse.gov/omb/fedreg/reproducible.html>, page 15 of 19. Needless to say, there are two issues involved here: (i) the times by which the initial decision maker and the appeals process must act; and (ii) assuming the complaint is granted, how quickly the Agency must act to implement the correction.

As for the initial decision process, BCI recommends 15 days for discrete factual errors and 45 days for all other asserted noncompliance (initial complaints) with the guidelines. As for the administrative appeal process, BCI recommends 45 days from the time the petition for review is filed until a decision on the appeal is rendered. In the case of initial decisions, EPA’s failure to act by the deadline would constitute a denial and would be automatically appealable to the Agency’s administrative appeal body. These timeframes refer to a decision on the merits, not some other type of response. EPA should be able to act more quickly on more easily resolved or urgent complaints.

Once a decision is made in favor of the complainant, EPA should correct the problems as expeditiously as possible but no later than 90 days unless truly exceptional circumstances warrant a longer delay.

b. The Administrative Correction Process

BCI wishes to emphasize that OMB’s guidelines require that the correction process applies to any information that the Agency “disseminates” on or after October 1, 2002. Paragraph III. 4 found at <http://www.whitehouse.gov/omb/fedreg/reproducible.html>, page 15 of 19. With this timeline in mind, BCI believes that each program office within EPA should designate a person (or persons) (“Information Quality Coordinator(s)”) who would serve as the initial decision maker on complaints. Creation of such a position would promote consistency in decision-making and ensure that decision makers have some familiarity with the substance of the

issue. Under no circumstances should the “data owner” be the initial decision maker, unless that term is defined as the relevant program office.

The Information Quality Coordinator would be responsible for providing a written explanation, within the relevant timelines above, on any decision to approve or deny a request. For purposes of OMB reporting, the Office of Environmental Information (“OEI”) would be responsible for keeping a central record of all complaints received and decisions made.

As to the administrative appeal process, OMB states that “[a]n objective process will ensure that the office that originally disseminates the information does not have responsibility for both the initial response and resolution of a disagreement.” <http://www.whitehouse.gov/omb/fedreg/reproducible.html>, page 13 of 19. Yet the Draft Data Quality Guidelines make the EPA program or office that had original responsibility for the information responsible for resolution of the appeal. This is flatly inconsistent with the OMB guidelines.

BCI believes that the appellate decision maker should be the Deputy Administrator. She could delegate this function to a tribunal made up of Assistant Administrators (or their staffs) from program offices not involved in the dispute. Once a petition for review of an initial complaint is received the appellate decision maker could solicit written comments from the program office involved, review the appeal petition, the initial decision and any comments received from the program office. Any decision on the appeal should be made within the relevant timelines discussed above.

4. Other Issues of Concern

There are three other issues of concern to BCI that bear directly on whether EPA’s adoption of the OMB guidelines will have the intended result of ensuring that scientific information the Agency disseminates and bases its regulatory actions upon will be of the highest quality and caliber. They include EPA’s discretion to opt itself out of the requirements of the guidelines; the Agency’s discretion to elect not to correct information that does not meet the requirements of the guidelines; and whether the comment process in proposed rules should be considered commensurate with filing a complaint to initiate the administrative correction process.

As to the first issue, the Agency states that “[t]he guidelines may not apply to a particular situation based on the circumstances, and EPA retains the discretion to adopt approaches on a case-by-case basis that differ from the guidelines, where appropriate.” <http://www.epa.gov/oei/qualityguidelines/igq-background.htm> at 13. The Agency further states that “[f]actors such as imminent threats to public health or homeland security, statutory or court-ordered deadlines, or other time constraints, may limit or preclude the applicability of these guidelines.” *Id.* While the OMB guidelines are silent as to whether an Agency can opt out of having to adhere to its guidelines, it seems reasonable to allow a **limited** exemption for issues involving imminent threats and national security.

Such an exemption should be narrowly tailored to exempt the Agency from having to meet the Data Quality Guidelines in situations involving imminent threats to human health or homeland security. Under no circumstances should the exemption be any broader; it should not apply to statutory or court-ordered deadlines or so-called other time constraints. Otherwise, the exemption will undermine the intent of the OMB guidelines of ensuring that Agency regulatory decisions are based upon scientific information that is of the highest quality.

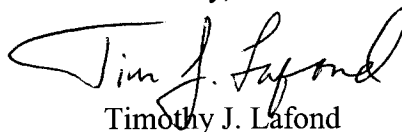
As to the second issue, BCI can see no valid reason why the Agency should be allowed to opt out of having to correct information that is found not to be in compliance with the Data Quality Guidelines. The very purpose of the administrative correction mechanism is to allow the timely correction of information that is not in conformance with the OMB guidelines. Allowing itself to opt-out of having to correct information products, does nothing more than allow the Agency and its program offices to circumvent one of the key purposes of the OMB guidelines.

Finally, as to the third issue, BCI believes that the comment process on the proposed rules is not commensurate with filing a complaint under the administrative correction mechanisms. BCI notes that concern over the information used by federal agencies in rulemaking was one of the main reasons Congress adopted Section 515 of the Treasury and Postal Appropriations Act for Fiscal Year 2001 (P.L. 105-554) directing OMB to issue government wide guidelines. Moreover, the fact that OMB guidelines are silent on this issue suggests to BCI that OMB envisioned an administrative correction process other than routine notice and comment rulemaking. BCI, therefore, would encourage the Agency to allow affected persons to file complaints for the correction of information contained in proposed rules separate of comments filed on the proposal.

CONCLUSION

BCI appreciates the opportunity to submit comments on the Agency's Data Quality Guidelines. If you have any questions on these comments, please do not hesitate to call me at (414) 524-2745 or BCI's counsel, Edward Ferguson, at (202) 383-6930.

Sincerely,

A handwritten signature in black ink, appearing to read "Tim J. Lafond". The signature is fluid and cursive, with a large initial "T" and "L".

Timothy J. Lafond

Chairman, BCI Environmental Committee